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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,283	10/30/2000	Benjamin Oshlack	200.1116US	1434

23280 7590 09/03/2002

DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 SEVENTH AVENUE, 14TH FLOOR  
NEW YORK, NY 10018

EXAMINER
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CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 09/03/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

**Office Action Summary**Application No.  
**09/702,283**Applicant(s)  
**Oshlack et al.**Examiner  
**Bennett Celsa**Art Unit  
**1627**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-41 \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 1627

### **DETAILED ACTION**

Claims 1-41 are currently pending.

#### ***Election/Restriction***

1. Claims 1-41 are generic to a plurality of disclosed patentably distinct species comprising different species of hydrocodone formulations comprising

A different species of oral dosage forms (e.g. tablets, capsules, caplets etc.) comprising

B. different species of patentably distinct components:

“suitable controlled-release materials” (see spec. pages 13-14;

“binder material(s)” (see spec. page 14); and optionally one or more

“diluent, lubricants ... glidants” (see spec page 15) etc.

Accordingly, the possible innumerable combinations of various components of different hydrocodone pharmaceutical components having different structures, chemical/biological properties, which are capable of separate manufacture and/or use; and require different and individually burdensome manual and/or computer structure and bibliographic searches in patent/nonpatent databases. The claims, as is, contain compositions which only comprise hydrocodone as a claimed ingredient and pharmaceutical parameters (delayed release profile) which preclude a meaningful and/or complete search on the merits.

Art Unit: 1627

. Applicant is required under 35 U.S.C. 121 to elect:

A. A single disclosed species of oral dosage form AND

B. A single hydrocodone formulation capable of achieving the presently claimed pharmaceutical attributes (e.g. delayed release profile). To satisfy this election *applicant may elect an example* from the specification which specifically describes the additional components (e.g. other than hydrocodone) which meets a claimed delayed release profile. .

In order to be completely responsive, applicant MUST indicate the claims which are readable on the elected invention.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1627

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane (art unit 1627), can be reached at (703)308-4537.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)  
August 28, 2002

**BENNETT CELSA  
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Bennett Celsa', is written over the printed name and title.